

ESTABLISHING THE RELATIONSHIP BETWEEN THE ULCERATIVE COLITIS DISEASE ACTIVITY INSTRUMENT (UCDAI) AND PATIENT HEALTH RELATED QUALITY OF LIFE FROM A LARGE RANDOMISED CONTROLLED TRIAL

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OBJECTIVES: The purpose of this study was to conduct a statistical mapping between standard assessments of disease severity in ulcerative colitis (UC) using the ulcerative colitis disease activity index (UCDAI) and a patient reported generic health-related utility instrument to estimate patient preference-based health utility. **METHODS:** Multinomial logistic regression was used to estimate response probabilities to each of the five domains of the EuroQol-5D index instrument (EQ-5D) from assessments of UC severity using the original UCDAI and an abbreviated (ie. No endoscopy) UCDAI instrument in patients enrolled into a clinical trial studying the use of oral/rectal mesalazine combination maintenance therapy. Predicted EQ-5D health utility was estimated by Monte Carlo bootstrap simulation. The predictive ability of the response mapping was assessed by comparing estimated and directly measured utility derived from the UK tariff (Dolan, 1997). **RESULTS:** Evaluable data were available for 128 patients, 59% of whom were male, and for which the median age at screening was 43.5 years (IQR 30 to 54). Using UCDAI item responses as predictor variables, the percentage of variance in domain response attributable to predictor variable change ranged from 20.4% (ANXIETY/DEPRESSION) to 42.5.5% (SELF CARE). Summary UCDAI score was a less effective predictor of the same domains ($R^2 = 13.2\%$ and 20.4% respectively). Items from the abbreviated UCDAI (no endoscopy score) showed comparable explanatory performance (R^2 range 21.3% to 38.0%). The mean utility predicted by the UCDAI item algorithm was 0.844 (sd 0.104) and 0.852 (sd 0.175) by estimation directly from EQ-5D responses ($p = 0.238$). The mean squared error (MSE) between the actual and predicted utilities was 0.019. Predicted EQ-5D utility was within 3% of the actual utility in 38.1% of cases and within 10% of the actual utility in 58.5% of cases. **CONCLUSIONS:** In this study response mapping of UC disease activity to EQ-5D domains produced reliable estimates of preference-based health-related utility. The near-identical explanatory power of models using either the original or abbreviated UCDAI assessment suggests that endoscopy adds little information to patient perception of UC disease severity. The results from this study will enable future investigators to generate health-related utility from the UCDAI in trials where this data was not prospectively collected.

PGI25

METHODS: The sample consisted of Spanish IBD patients completing the Spanish versions of IBDQ and EQ-5D. EQ-5D scores were estimated using the Spanish tariffs. Algorithms for estimating utilities based on responses to IBDQ were derived for combined IBD population and then separately for CD and UC patients using a stepwise forward OLS regression. The algorithms consisted of a combination of important patient characteristics and significant IBDQ domains. Adjusted R-square and root mean-squared error (RMSE) were used to select the most appropriate algorithm. The ability of the algorithm based on IBD patients to predict the utilities for CD and UC patients was assessed. **RESULTS:** The sample consisted of 424 IBD patients with a mean age of 35 years and median disease duration of 4.33 years. Disease severity (Harvey-Bradshaw/Rachmilewitz index) was correlated with IBDQ ($r = -0.75$) and EQ-5D ($r = -0.58$). **CONCLUSIONS:** This regression approach enables clinicians and decision makers to estimate preference based utilities from IBDQ in IBD patients. The algorithm appears to be fairly robust based on the explanatory power of the algorithm and validation results.

PGI27

PSYCHOMETRIC VALIDATION OF TRANSLATION TO SPANISH OF THE REFLUX DISEASE QUESTIONNAIRE (RDQ) AND GASTROINTESTINAL IMPACT SCALE IN PATIENTS WITH GASTROESOPHAGEAL REFLUX DISEASE (GERD)

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OBJECTIVES: The study aims to document the psychometric characteristics of the Spanish translation of two questionnaires: RDQ to evaluate GERD symptoms and GIS to evaluate impact of symptoms in patients' daily life. **METHODS:** A psychometric validation study to evaluate two self-administered questionnaires in 300 patients with reflux symptoms. Each investigator conducted the study on two consultations (basal/2 weeks visits) in one patient with GERD diagnosis and no predictable changes in their health status in the following 16 days (reliability group) and 4 new patients to be treated with a known efficient treatment (sensitivity group). **RESULTS:** A total of 281 evaluable patients were analysed; mean age was 55.6 years (95% CI: 53.9–57.3) and 48% were male. Feasibility: More than 80% of patients complete the RDQ (100% Visit 1 and 99.6% Visit 2) and 99.3% GIS questionnaire (both visits). Only 0.71% patients left one missing item in the RDQ and 1.07% in the GIS questionnaire. Validity: RDQ and GIS questionnaires are able to discriminate frequency and sensibility of symptoms ($p < 0.0001$). Reliability of internal consistency: Both questionnaires have a good internal consistency. RDQ showed an alpha value (Cronbach) ≥ 0.70 and CCI ≥ 0.60 in all domains. GIS questionnaire had an alpha value ≥ 0.69 and CCI ≥ 0.45 in all domains. Sensibility to change (sensitivity group): Both questionnaires show a high sensibility to the patient recovery. When the either the physician or the patient found an improvement in the health at two weeks, the differences in the scores were always statistically significant ($p < 0.0001$). **CONCLUSIONS:** RDQ and GIS questionnaires have satisfactory reliability, validity and sensibility to change. Both tools are easy to use and suitable to evaluate the impact and the severity of reflux symptoms in GERD patients.

PGI28

DERIVING PREFERENCE BASED UTILITIES FOR CD AND UC PATIENTS: CONVERTING IBDQ INTO EQ-5D UTILITIES

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BACKGROUND: Inflammatory Bowel Disease Questionnaire (IBDQ) is a disease specific instrument widely used to assess quality of life (QoL) of patients with inflammatory bowel disease (IBD) particularly patients with Crohn's Disease (CD) and Ulcerative Colitis (UC). However, decision makers require preference based utilities to allocate health care resources when only QoL data estimated using IBDQ is available. **OBJECTIVES:** To derive an algorithm capable of generating preference based utilities for IBD patients based on their QoL assessed using IBDQ and to estimate its applicability to CD and UC patients separately.

DEVELOPMENT AND PSYCHOMETRIC VALIDATION OF A NEW QUESTIONNAIRE MEASURING THE IMPACT OF CHILD GASTROENTERITIS ON PARENTS

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OBJECTIVES: To define the scoring and assess the psychometric properties of a newly developed questionnaire measuring the